

I. Restriction Requirement Under 35 U.S.C. §121 and 372

The Examiner has required a restriction of the claims to one of the following categories:

Group I. Claims 1 and 12, drawn to compositions and use.

Group II. Claims 2-8, 10 and 13, drawn to compounds and composition.

Group III. Claim 9, drawn to multiple processes of preparing.

Claim 11 is drawn to nonstatutory subject matter and hence cannot be grouped.

The Examiner maintains the above grouping is proper because the inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1, because under PCT Rule 13.2, they lack the same or corresponding special technical feature. The Examiner also requests a tentative election of a single species. Applicants traverse the restriction requirement and election of a single species.

Applicants submit that the standard applicable to the instant application is not one of restriction practice under U.S. guidelines, but one of Unity of Invention under the PCT. In the instant case, no lack of Unity of Invention was found by the International Searching Authority or the International Preliminary Examining Authority. Here, all claims were searched and examined as one invention. The question of unity of invention may be reexamined only within the scope of the rules of the Patent Cooperation Treaty (35 U.S.C. §372(b)), and restriction requirements made according to U.S. practice are in error. Patent Cooperation Treaty Article 27 states that "no national law shall require compliance with requirements relating to form or contents ... different from or additional to those which are provided for this Treaty and the Regulations." Therefore, the Examiner must find error in the way the rules were applied by the International Search Authority.

The reasons given for the instant restriction requirements pertain only to U.S. practice since they are based primarily on distinctiveness. PCT Rule 13.1 includes within the definition

of Unity of Invention "a group of inventions so linked as to form a general inventive concept." Accordingly, patentably distinct inventions do not lack unity of invention as long as they derive from the same inventive concept. Consequently, distinctiveness, as used in U.S. practice, is not a sufficient criterion for holding of lack of unity of invention or for a restriction requirement under 35 U.S.C. §372(b). What is required for a holding of lack of unity is that the inventions be truly "independent". This is the standard for lack of unity applied by the court *In re Harnisch*, 206 U.S.P.Q. 300, 306 (CCPA 1980) ("unity of invention" ... applies where unrelated inventions are involved'). Independent, as defined in MPEP 802.01, "means that there is not a relationship between the two or more subjects disclosed, that is, they are unconnected in design, operation, or effect."

Applicants assert that the inventions of Groups I-III do relate to a single general inventive concept because all of the claims relate to the core concept of treating bacterial infections. The compounds, process of making, and method of use are so connected as to have arisen from a singular research effort. Accordingly, the claims read on a plurality of distinct but related inventions and fully complies with the unity of invention requirement of the PCT. Applicants further assert that the compounds do share a significant distinguishing structural feature. This feature is the novel R3 substituent. In light of the above arguments, the inventions of Groups I-III must be included in a single application. Therefore, the Examiner is respectfully requested to reconsider and withdraw the restriction requirement with respect to Groups I-III.

However, solely to expedite prosecution of the application, Applicants elect, with traverse, the invention of Group I, claims 1 and 12, drawn to compositions and use. Applicants further elect with traverse the single species, [3R, 4R]-1-Heptyl-3-(carboxymethyl)-4-[3-(6-methoxyquinolin-4-yl) propyl] piperidine, given in example 6, page 29 of the specification.

Applicants traverse the restriction requirement on the ground that the inventions of the claims as grouped by the Examiner are not independent, but applicants do not traverse this requirement on the ground that these inventions are not patentably distinct. Thus, Applicants are not aware of any evidence that the claims are obvious variants of each other and specifically deny that the inventions of any groups of claims are obvious variants of the inventions of any other groups of claims.

II. Conclusion

This reply is intended to further this case to allowance by addressing each ground of objection and rejection in the Examiner's Office Action. Reconsideration of this application is requested. Should the Examiner have any questions regarding this application, the Examiner is invited to call the undersigned agent at the number given below.

Respectfully submitted,



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